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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,190	11/25/2003	Malka Berndt	06530.0317	4220

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,190	BERNDT, MALKA	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☒ Claim(s) *9-10, 20-21, and 28-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 9-10, 20-21, and 28-29 are objected to because of the following informalities: The preceding claims use the language "one of" but then use the non-alternative term "and." Using the language "one of" is interpreted to mean that only one of the specified elements is necessary. Therefore, use of the alternative term "or" is required to make the meaning clear. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Slater et al. (U.S. Pat. No. 5,359,993).

Regarding claim 1, Slater et al. disclose a device to perform a medical procedure comprising:

a medical device 200 (col. 1, ln. 7 and Fig. 4); and

an indicator 10 produced directly on the medical device (col. 7, ln. 59-61 and Fig. 4), the indicator capable of undergoing a color change when exposed to a particular environment (col. 12, ln. 55-67).

Regarding claim 2, Slater et al. disclose the device of claim 1, wherein the medical device comprises a handle 204, a distal end effector, and an elongate portion 202 connecting the handle to the distal end effector (col. 7, ln. 1-5 and Fig. 4).

Regarding claim 3, Slater et al. disclose the device of claims 1 and 2, wherein the indicator 10 is produced directly on the handle 204 (col. 7, ln. 59-61 and Fig. 4).

Regarding claim 4, Slater et al. disclose the device of claims 1 and 2, wherein the handle 204 comprises a ring portion and an elongate portion (Fig. 4).

Regarding claim 6, Slater et al. disclose the device of claim 1, wherein the indicator is printed directly on the medical device. Slater et al. disclose color indicators that are located directly on the medical device (col. 12, ln. 55-67), and the process of printing is inherently used to apply color to a surface. Furthermore, applicant discloses that "any suitable method of printing may be used" in paragraph 26 of the specification.

Regarding claim 7, Slater et al. disclose the device of claim 1, wherein the indicator is configured to show a symbol when it undergoes the color change (col. 13, ln. 5-7).

Regarding claim 8, Slater et al. disclose the device of claim 1, wherein the particular environment includes a chemical (col. 2, ln. 41-45).

Regarding claim 9, Slater et al. disclose the device of claims 1 and 8, wherein the chemical is EtO gas (col. 2, ln. 41-45).

Regarding claim 10, Slater et al. disclose the device of claim 1, wherein the particular environment includes steam or dry heat (col. 2, ln. 41-45). Slater et al.

disclose sterilizing medical instruments by autoclaving, and it is well known in the art that autoclaving can use steam and/or dry heat.

Regarding claim 11, Slater et al. disclose the device of claim 1, wherein the indicator is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment (col. 12, ln. 65-67).

Regarding claim 12, Slater et al. disclose the device of claim 1, wherein the indicator is configured to be a different color than a portion of the medical device after being exposed to the particular environment (col. 12, ln. 65-67).

Regarding claim 13, Slater et al. disclose the device of claim 1, wherein the indicator is produced directly on a surface of the medical device (col. 7, ln. 59-61 and Fig. 4).

Regarding claim 14, Slater et al. disclose the device of claim 1, wherein the indicator includes a plurality of indicators (col. 12, ln. 65-67).

Regarding claim 15, Slater et al. disclose the device of claims 1 and 14, wherein each of the plurality of indicators undergoes a color change different from the other of the plurality of indicators (col. 12, ln. 65-67). Slater et al. disclose a color code with a sequence of colors, wherein each color is a different indicator, and each color indicator is capable of changing to a different color indicator.

Regarding claim 16, Slater et al. disclose a medical device comprising:

a handle 204 (Fig. 4);

a distal end effector (col. 7, ln. 1-5);

an elongate portion 202 connecting the handle 204 to the distal end effector (col. 7, ln. 1-5 and Fig. 4); and

a visual indicator 10 produced directly on a surface of the handle (col. 7, ln. 59-61 and Fig. 4),

wherein the indicator is configured to be substantially the same color as the surface of the handle before being exposed to a particular environment (col. 12, ln. 65-67), and

wherein indicator is configured to be a different color than the surface of the handle after being exposed to the particular environment (col. 12, ln. 65-67).

Regarding claim 17, Slater et al. disclose the device of claim 16, wherein the indicator is printed directly on the medical device. Slater et al. disclose color indicators that are located directly on the medical device (col. 12, ln. 55-67), and the process of printing is inherently used to apply color to a surface. Furthermore, applicant discloses that "any suitable method of printing may be used" in paragraph 26 of the specification.

Regarding claim 18, Slater et al. disclose the device of claim 16, wherein the indicator is configured to show a symbol when it undergoes the color change (col. 13, ln. 5-7).

Regarding claim 19, Slater et al. disclose the device of claim 16, wherein the particular environment includes a chemical (col. 2, ln. 41-45).

Regarding claim 20, Slater et al. disclose the device of claims 16 and 19, wherein the chemical is EtO gas (col. 2, ln. 41-45).

Regarding claim 21, Slater et al. disclose the device of claim 16, wherein the particular environment includes steam or dry heat (col. 2, ln. 41-45). Slater et al. disclose sterilizing medical instruments by autoclaving, and it is well known in the art that autoclaving can use steam and/or dry heat.

Regarding claim 22, Slater et al. disclose the device of claim 16, wherein the indicator includes a plurality of indicators (col. 12, ln. 65-67).

Regarding claim 23, Slater et al. disclose the device of claims 16 and 22, wherein each of the plurality of indicators undergoes a color change different from the other of the plurality of indicators (col. 12, ln. 65-67). Slater et al. disclose a color code with a sequence of colors, wherein each color is a different indicator, and each color indicator is capable of changing to a different color indicator.

Regarding claim 24, Slater et al. disclose a method of determining a state of a medical device, the method comprising:

providing a medical device 200 (col. 1, ln. 7 and Fig. 4) having an indicator 10 produced directly on a portion of the medical device (col. 7, ln. 59-61 and Fig. 4), the indicator capable of undergoing a color change when exposed to a particular environment (col. 12, ln. 55-67); and

viewing the medical device to determine if the indicator has changed color due to exposure to the particular environment (col. 12, ln. 55 – col. 13, ln. 7).

Regarding claim 25, Slater et al. disclose the method of claim 24, wherein providing a medical device includes providing a medical device with an indicator printed directly on a portion of the device. Slater et al. disclose color indicators that are located

directly on the medical device (col. 12, ln. 55-67), and the process of printing is inherently used to apply color to a surface. Furthermore, applicant discloses that "any suitable method of printing may be used" in paragraph 26 of the specification.

Regarding claim 26, Slater et al. disclose the method of claim 24, wherein viewing the medical device includes determining if there is a symbol on the device (col. 12, ln. 55 – col. 13, ln. 7).

Regarding claim 27, Slater et al. disclose the method of claim 24, wherein the particular environment includes a chemical (col. 2, ln. 41-45).

Regarding claim 28, Slater et al. disclose the method of claims 24 and 27, wherein the chemical is EtO gas (col. 2, ln. 41-45).

Regarding claim 29, Slater et al. disclose the method of claim 24, wherein the particular environment includes steam or dry heat (col. 2, ln. 41-45). Slater et al. disclose sterilizing medical instruments by autoclaving, and it is well known in the art that autoclaving can use steam and/or dry heat.

Regarding claim 30, Slater et al. disclose the method of claim 24, wherein viewing the medical device includes determining if the indicator is substantially the same color as the portion of the medical device (col. 12, ln. 65-67).

Regarding claim 31, Slater et al. disclose the method of claim 24, wherein viewing the medical device includes determining if the indicator is a different color than the portion of the medical device (col. 12, ln. 65-67).

Regarding claim 32, Slater et al. disclose the method of claim 24, wherein the medical device includes a plurality of indicators and viewing the medical device includes

determining if any one of the plurality of indicators has changed color. Slater et al. disclose a color code with a sequence of colors, wherein viewing the medical device includes determining if any one of the color indicators has changed color to a different color indicator (col. 12, ln. 65-67).

Regarding claim 33, Slater et al. disclose the method of claim 24, wherein the medical device 200 comprises a handle 204, a distal end effector, and an elongate portion 202 connecting the handle to the distal end effector (col. 7, ln. 1-5 and Fig. 4); and

wherein the indicator 10 is produced directly on the handle 204 (col. 7, ln. 59-61 and Fig. 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al.

Regarding claim 5, Slater et al. disclose the device of claims 1, 2, and 4, wherein the indicator 10 is produced directly on the handle 204 (col. 7, ln. 59-61 and Fig. 4). The claim differs from Slater et al. in calling for the indicator to be produced specifically on the ring portion of the handle. Slater et al., however, disclose that the indictor can be mounted in a different location (col. 7, ln.59-62).

Therefore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the indicator of Slater et al. specifically on the ring portion of the handle because applicant has not disclosed that placing the indicator specifically on the ring portion of the handle uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that is not achieved by Slater's placement of the indicator. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with Slater's placement of the indicator because both locations are on the handle of the medical device and easily visible.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 4,382,063 to Romito et al.
U.S. Pat. No. 5,518,927 to Malchesky et al.
U.S. Pat. No. 6,218,189 B1 to Antonoplos et al.

U.S. PGPub 2004/0049172 A1 to Root et al.
U.S. PGPub 2004/0265778 A1 to Kliff et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
8/19/05

MICHAEL PEFFLEY
PRIMARY EXAMINER